Memorial Sloan Kettering Cancer Center

Policy Change to Improve Evidence Development for Older Adults with Cancer

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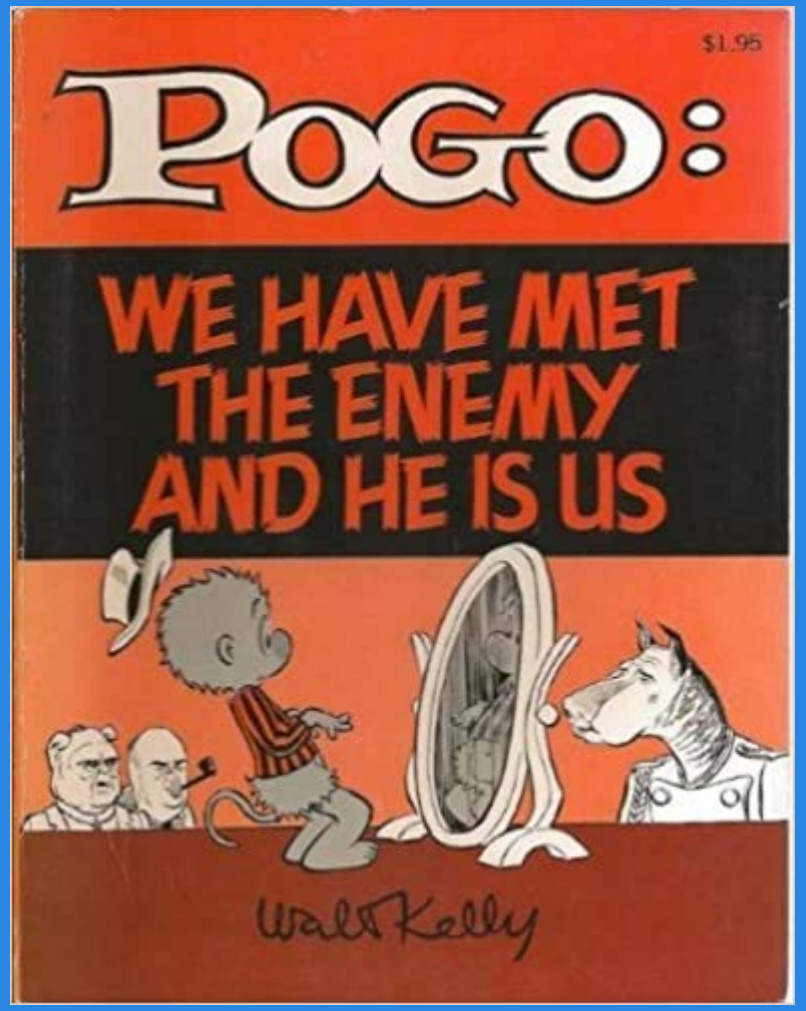
Subtitle

- “If not us, who? If not now, when?”

COI

- none

The struggle for Geriatric Oncology



- We need the data
- We know how to get it

- But we’re not doing it
- Not designing studies for older patients
- When available, often not recommending studies

Conclusion from 1983 meeting-Yancik

CONCLUSION: THE MESSAGE OF THE CONFERENCE

Conferees agreed that information about the relationship of cancer and aging as these two fields intersect in clinical medicine is extremely limited. Not that much is known about either field alone; even less is known when they are linked. Research on cancer prevention for the elderly (i.e., before these people

1. **Examination of the factors unique to older-aged persons…**
2. **Baseline data…clinical interface of cancer and aging**
3. **Interdisciplinary team approach far greater than an occasional collaboration**

treatment, rehabilitation, and continuing care. The conference message calls for some vigorous rethinking of clinical research objectives in both cancer and aging.

GUIDANCE DOCUMENT

Study of Drugs Likely to be used in the Elderly

NOVEMBER 1989

Download the Final Guidance Document

CENTER FOR DRUG EVALUATION AND RESEARCH

Guidance for Industry

The FDA published Good Guidance Practices in February 1997.
This guidance was developed and issued prior to that date.

FDA Guidance Document--1989

III. INCLUSION OF ELDERLY PATIENTS IN CLINICAL STUDIES

The patients included in clinical studies should, in general, reflect the population that will receive the drug when it is marketed. Therefore, for drugs likely to be used in the elderly, older patients should be included in clinical trials in reasonable numbers. Although it is appropriate and necessary to exclude patients on the basis of functional characteristics that make it impossible for them to be safely, ethically, and usefully included (e.g., patients who are too infirm to participate, too medically complicated to permit interpretation of results, too likely to suffer serious intercurrent illness, or unable to provide meaningful informed consent), exclusions should not be arbitrary. Moreover, exclusions deemed

GUIDANCE DOCUMENT

Inclusion of Older Adults in Cancer Clinical Trials

Draft Guidance for Industry

MARCH 2020

Download the Draft Guidance Document | Read the Federal Register Notice

Potential role of FDA. Ideas under repeated discussion.

- Carrot and stick approach and proposals

  – Prolong the patent life
  – Drug approval with expansion trials, i.e. looking for toxicity, functional subsets, just the older patient
  – Eligibility to account for comorbidity
  – **<u>Unfortunately, nothing has worked</u>**

We unequivocally know…

- Older patients with cancer are different and more complex than younger patients
- Performance status is an inadequate measure of older cancer patients
- Some form of cancer directed geriatric assessment gives valuable information for the care of patients
- Prospective data confirms the benefit (ASCO 2020)
- We need much more data as treatments become more complex and the population increases
- **We know how to obtain that data….**

We know how to do it...

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JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

Improving the Evidence Base for Treating Older Adults With Cancer: American Society of Clinical Oncology Statement

Arti Hurria, Laura A. Levit, William Dale, Supriya G. Mohile, Hyman B. Muss, Louis Fehrenbacher, Allison Magnuson, Stuart M. Lichtman, Suanna S. Bruinooge, Enrique Soto-Perez-de-Celis, William P. Tew, Michael A. Postow, and Harvey J. Cohen

VOLUME 36 · NUMBER 22 · AUGUST 1, 2018

JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

Practical Assessment and Management of Vulnerabilities in Older Patients Receiving Chemotherapy: ASCO Guideline for Geriatric Oncology

Supriya G. Mohile, William Dale, Mark R. Somerfield, Mara A. Schonberg, Cynthia M. Boyd, Peggy S. Burhenn,

Universal Dataset-Mohile, et al. JCO 2018

Box 2: Summary of a Minimum Data Set for Practical Assessment of Vulnerabilities in Older Patients With Cancer

See Table 1 for more details and rationale.

1. Predict chemotherapy toxicity (if clinically applicable): Cancer and Aging Research Group or Chemotherapy Risk Assessment Scale for High-Age Patients tools
2. Estimate (noncancer) life expectancy (if clinically applicable): ePrognosis
3. Functional assessment: instrumental activities of daily living
4. Comorbidity assessment: medical record review or validated tool
5. Screening for falls, one question: how many falls or falls with an injury have you had in the previous 6 months (or since your last visit)?
6. Screening for depression: Geriatric Depression Scale or other validated tool
7. Screening for cognitive impairment: Mini-Cog or Blessed Orientation-Memory-Concentration test
8. Screening for malnutrition: weight loss/body mass index

- Simple measures
- Simple questions
- Watch the patient walk
- Weight loss
- Depression
- Where do they live; dependent/independent
- Adaptable to clinical trials

Adapting eligibility

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JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

Broadening Eligibility Criteria to Make Clinical Trials More Representative: American Society of Clinical Oncology and Friends of Cancer Research Joint Research Statement

Edward S. Kim, Suanna S. Bruinooge, Samantha Roberts, Gwynn Ison, Nancy U. Lin, Lia Gore, Thomas S. Uldrick, Stuart M. Lichtman, Nancy Roach, Julia A. Beaver, Rajeshwari Sridhara, Paul J. Hesketh, Andrea M. Denicoff, Elizabeth Garrett-Mayer, Eric Rubin, Pratik Multani, Tatiana M. Prowell, Caroline Schenkel, Marina Kozak, Jeff Allen, Ellen Sigal, and Richard L. Schilsky

Eligibility addressing realities..

JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

Modernizing Clinical Trial Eligibility Criteria: Recommendations of the American Society of Clinical Oncology–Friends of Cancer Research Organ Dysfunction, Prior or Concurrent Malignancy, and Comorbidities Working Group

Stuart M. Lichtman, R. Donald Harvey, Marie-Anne Damiette Smit, Atiqur Rahman, Michael A. Thompson, Nancy Roach, Caroline Schenkel, Suanna S. Bruinooge, Patricia Cortazar, Dana Walker, and Louis Fehrenbacher

If not now…when?

40 years of discussion of need

Multiple prospective studies showing benefit of geriatric evaluation

Multiple position papers and guidance

Multiple organizations emphasizing research and promoting the geriatric oncology agenda

ASCO, SIOG, ESMO
CALGB/Alliance, GOG/NRG
CARG

Deficiencies

- Lack of integration of geriatric principles into oncology practice
- Investigator initiated research does not include the necessary baseline geriatric assessment
- Pharma has been unwilling to incorporate geriatric principles or do specific studies for older patients
- Journals not insisting on the report of this data
- Clinicians often not encouraging the participation of older patients on clinical trials

Suggested initiatives

1	2	3
Physician education needs to be expanded from medical school onwards	Professional societies need to continue to emphasize these issues	Major role of the FDA • Over the years a carrot and stick approach has been discussed

We have the ability to move forward…

- The multiple stakeholders are working together
- International oncology societies have had input
- Multiple recommendations and taskforces have been published and discussed
- Multiple investigators are invested in this area

If not now, when?

- **The answer can only be: now!!**

- The clinical trial infrastructure and regulatory bodies needs to require this—FDA needs to be more stringent
- The high impact journals need to require the analysis
- Insurers need to recognize the time this will take
- Reimburse patient expenses, i.e. travel, parking at the least

If not now, when?

- Incentive clinicians to put patients on study
- Use information technology
  - Simplify data acquisition and recording
  - Can be used to assess function
  - Database
- Clinical trial design
  - Patient/physician choice
  - Minimize visits, tests

Final thoughts

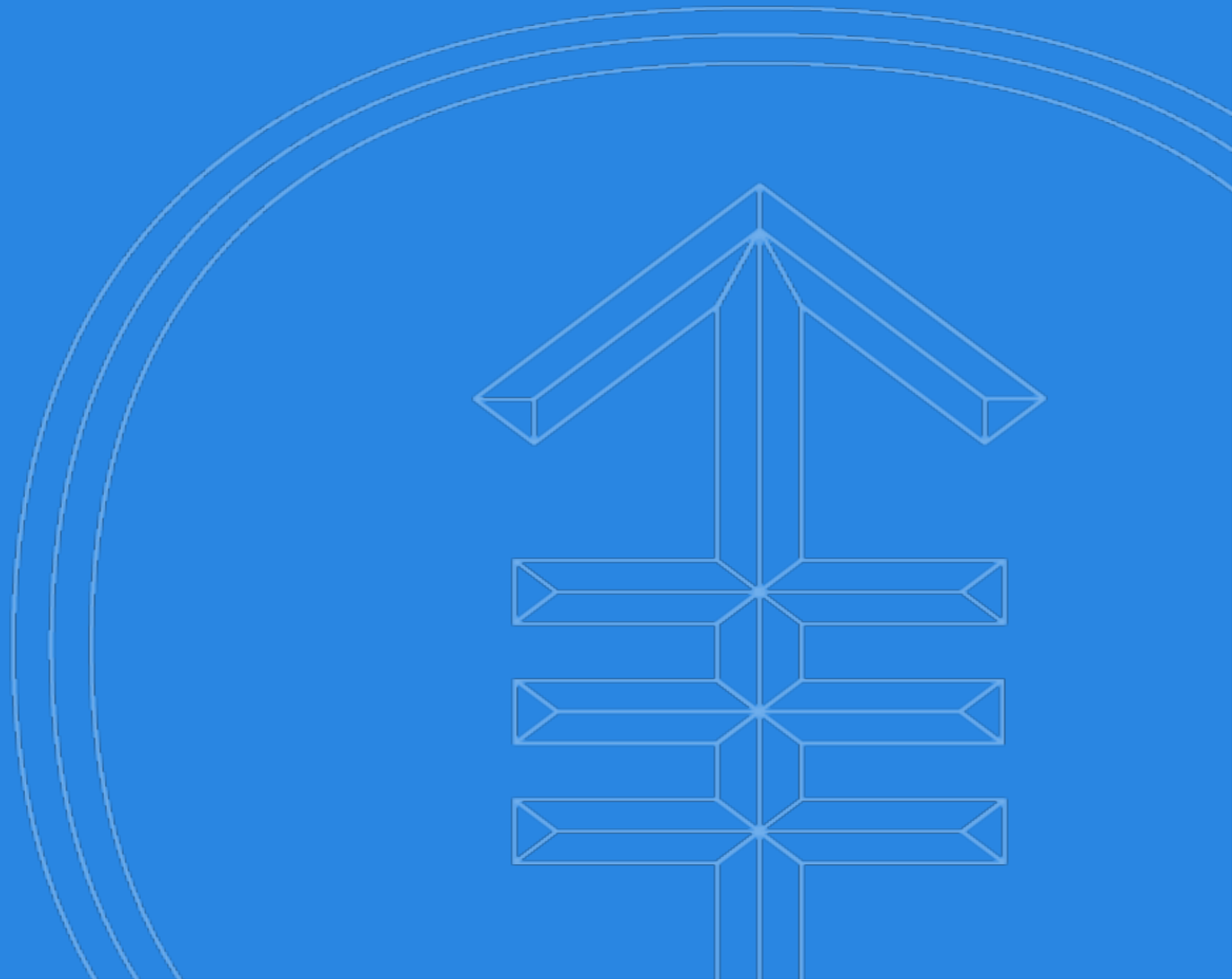
- This expanding, largely vulnerable population needs to be the focus of our endeavors. They deserve nothing less.

Do not cast me away when I am old; do not forsake me when my strength is gone.

Psalms 71.9

Memorial Sloan Kettering Cancer Center

Thank you



Groundhog Day Effect

It is the idea that every action that one makes; the rewards and consequences of those actions are not followed through the next day. Therefore this pattern can keep on repeating for an unknown amount of time.